No. 06-1047

In the Supreme Court of the United States

LISA ANN PAFFORD AND RICHARD LEON PAFFORD, PARENTS AND NEXT FRIENDS OF RICHELLE LORRAE PAFFORD, A MINOR, PETITIONERS

v.

MICHAEL O. LEAVITT, SECRETARY OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether special masters who conduct proceedings under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-1 *et seq.*, are inferior officers who may be appointed by a court of law or the head of a department, or instead are superior officers who must be nominated by the President and confirmed by the Senate.

2. Whether a deferential standard of review of the special masters' determinations violates the Fifth Amendment's Due Process Clause.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 57-78) is reported at 451 F.3d 1352. The opinion of the Court of Federal Claims (Pet. App. 24-56) is reported at 64 Fed. Cl. 19. The opinion of the Court of Federal Claims special master (Pet. App. 1-23) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on June 20, 2006. A petition for rehearing was denied on October 24, 2006 (Pet. App. 79-80). The petition for a writ of certiorari was filed on January 22, 2007. The

jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. Congress enacted the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or the Act), 42 U.S.C. 300aa-1 *et seq.*, to promote childhood immunization programs. The Act first creates a National Vaccine Program "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. 300aa-1. It then establishes a National Vaccine Injury Compensation Program (the Program), funded by a special tax on vaccines, under which "compensation may be paid for a vaccine-related injury or death." 42 U.S.C. 300aa-10(a); see 26 U.S.C. 9510.

A claimant under the Program is not required to demonstrate that a vaccine was defective or that its manufacturer was negligent. Instead, a claimant must establish causation in one of two ways. An injury is presumed to have been caused by a vaccine, and therefore to be compensable, if it is listed on the Program's Vaccine Injury Table (the Table), and first manifests within a set period of time, also prescribed by the Table, after administration of the vaccine. See 42 U.S.C. 300aa-11(c)(1)(C)(i), 300aa-13(a)(1)(A), 300aa-14(a); 42 C.F.R. 100.3(a). The presumption of causation, if it applies, may be rebutted by evidence that the injury was "due to factors unrelated to the administration of the vaccine." 42 U.S.C. 300aa-13(a)(1)(B). If a claimant's injury is not presumed compensable under the Table, the claimant may nonetheless obtain compensation by proving that the vaccine in fact caused or significantly aggra-

vated an injury. 42 U.S.C. 300aa-11(c)(1)(C)(ii), 300aa-13(a)(1)(A).

The compensation available under the Act includes unreimbursed medical expenses, rehabilitation, special education, vocational training, residential and custodial care, special equipment, lost earnings, pain and suffering, and attorneys' fees. 42 U.S.C. 300aa-15(a) and (e). A claimant who is dissatisfied with a Program award may reject the award and bring a civil action under state tort law, subject to certain limitations. 42 U.S.C. 300aa-11(a), 300aa-21. State statutes of limitations are tolled during the pendency of a Vaccine Act claim. 42 U.S.C. 300aa-16(c).

b. The Act establishes an office of special masters within the United States Court of Federal Claims (CFC), and specifies the duties of the special masters and the procedures by which they are to evaluate petitions for compensation. 42 U.S.C. 300aa-12(c). Within 30 days of the issuance of a special master's decision, the parties may seek review by the CFC. 42 U.S.C. 300aa-12(e). The CFC's decision may be reviewed by the Court of Appeals for the Federal Circuit. 42 U.S.C. 300aa-12(f).

As originally enacted, the Vaccine Act placed jurisdiction over Vaccine Act cases in the district courts of the United States. Vaccine Act, Pub. L. No. 99-660, Tit. III, § 2112(a), 100 Stat. 3761. It also provided that the special master would prepare and submit to the court proposed findings of fact and conclusions of law. § 2112(c)(2)(E), 100 Stat. 3762. The district court could consider any matter *de novo*. § 2112(d)(1), 100 Stat. 3762. Congress later amended the Act to confer jurisdiction over Vaccine Act petitions in the United States Claims Court, the CFC's predecessor. Vaccine Compen-

sation Amendments of 1987, Pub. L. No. 100-203, Tit. IV, Subtit. D, § 4307, 101 Stat. 1330-224 (42 U.S.C. 300aa-12).

In 1989, Congress amended the Vaccine Act again in order to correct "fundamental problems" in the "nature of the adjudication of petitions," and to "re-dedicat[e] * * * all parties to the creation of an expeditious, non-adversarial, and fair system." H.R. Rep. No. 247, 101st Cong., 1st Sess. 509 (1989). Under the amendments, a special master may issue a decision, including findings of fact and conclusions of law, rather than submitting proposed findings and conclusions of law to the CFC. 42 U.S.C. 300aa-12(d)(3). The CFC now reviews factual findings under the arbitrary-and-capricious standard, and reviews legal determinations for accordance with law. 42 U.S.C. 300aa-12(e)(2). That change in the standard of review reflects the expectation "that the Special Master and the powers given to the Master [would] allow the proceedings to be direct and straightforward." H.R. Rep. No. 247, *supra*, at 510.

2. On March 22, 2001, petitioners sought compensation under the Act on the ground that their daughter, Richelle Lorrae Pafford, first showed signs of systemic onset juvenile rheumatoid arthritis, also known as Still's disease, after receiving vaccinations. Gov't C.A. Br. 2; Pet. App. 1, 4. The timing of the onset of Richelle's Still's disease did not give rise to a presumption of compensability under the Vaccine Injury Table. *Id.* at 9. After considering the evidence, the special master concluded that petitioners had not shown by a preponderance of the evidence that Richelle's vaccinations actually caused her disease. *Id.* at 23. He accordingly denied compensation. *Ibid.*

3. The CFC sustained the special master's decision. Pet. App. 24-56. Following a thorough discussion of the special master's decision and the evidence of record, the CFC found that petitioners' claim lacked merit because petitioners failed: (1) to establish that the onset of Richelle's condition occurred within a medically accepted time frame from the date of vaccination, and (2) to address adequately the range of other potential causes of Richelle's condition suggested by the record. *Id.* at 51-55. With regard to petitioners' contention that the special master abused his discretion by failing to provide notice that he would consider the time frame issue, the CFC found that petitioners were on notice of the need for such proof. *Id.* at 50-51.

4. The court of appeals affirmed. Pet. App. 57-78. It held that petitioners had failed to produce evidence to establish the medically accepted time frame in which Still's disease might develop following vaccination and, therefore, failed to establish that Richelle's vaccinations caused her Still's disease. *Id.* at 64-65. The court noted that the record contained other known, contemporaneous events unrelated to the vaccinations that were just as likely as the vaccinations to cause Still's disease. *Id.* at 66-67.

The court of appeals also rejected petitioners' argument that the special master violated their due process rights by raising the temporal relationship issue *sua sponte* at the close of trial without providing a full and fair opportunity for petitioners to present evidence on that issue. Pet. App. 67-68. The court noted that the record demonstrated that petitioners were on notice of the temporal relationship issue well before the end of trial and had, in fact, presented medical testimony on that point. *Ibid.*

Judge Dyk dissented on causation. Pet. App. 68-78. He did not dissent on the due process issue. See *ibid.*

ARGUMENT

Petitioners seek (Pet. 10) a "sweeping, remedial exercise of this Court's supervisory jurisdiction" to review numerous aspects of the Vaccine Act Program. They assert (Pet. i) two specific legal challenges: an Appointments Clause challenge to the appointment of special masters by the judges of the CFC; and a Due Process Clause challenge to the standard of review under which the CFC reviews factual findings by special masters. As a remedy for those alleged violations, petitioners seek (Pet. 10) to impose "the strictures and procedural protections of the Administrative Procedure Act," along with uniform rules of pleading, proof, causation, and *stare decisis* that they consider to be lacking in the current system. The questions presented in the petition were neither pressed nor passed upon below. There is no conflict among the circuits on those issues, and petitioners' assertions lack merit in any event. Accordingly, further review is not warranted.

1. Petitioners first contend (Pet. 10-13) that the Vaccine Act violates the Appointments Clause because it authorizes special masters of the CFC to issue decisions that are not subject to *de novo* review in all respects by CFC judges.

a. Petitioners did not advance that claim below, and the lower courts did not reach it. This Court does not ordinarily consider claims that were neither pressed nor passed upon below. See, *e.g.*, *United States* v. *Williams*, 504 U.S. 36, 41 (1992). Petitioners note that this Court has on occasion considered similar constitutional issues that were raised for the first time in this Court. See

Pet. 7 & n.12, 8 n.14 (citing *Freytag* v. *Commissioner*, 501 U.S. 868, 879 (1991); *Glidden Co.* v. *Zdanok*, 370 U.S. 530, 535-536 (1962) (plurality opinion)). This is not, however, "one of those rare cases" warranting a departure from this Court's ordinary practice. See *Freytag*, 501 U.S. at 879. To the contrary, petitioners' broadside on numerous aspects of the carefully crafted Vaccine Act compensation system only underscores one of the reasons this Court does not ordinarily address claims in the first instance—even if the questions presented otherwise warranted this Court's review, the Court would benefit from the views of the lower courts that administer this compensation scheme, pursuant to Congress's grant of exclusive jurisdiction.

b. In any event, petitioners' Appointments Clause challenge lacks merit. The Appointments Clause provides that the President:

> shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: *but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.*

U.S. Const. Art. II, § 2, Cl. 2 (emphasis added). By directing the judges of the CFC to appoint special masters (42 U.S.C. 300aa-12(c)(1)), Congress exercised its authority under the Appointments Clause to vest the appointment of special masters in that body. This Court has consistently upheld similar exercises of appointing

authority. See *Freytag*, 501 U.S. at 883, 890-892 (holding that the Tax Court is a court of law that may appoint special trial judges to hear certain tax cases); *id.* at 901 (Scalia, J., concurring in part and in the judgment) (concluding that the Chief Judge of the Tax Court is the head of a department who may appoint inferior judges); *Edmond* v. *United States*, 520 U.S. 651, 666 (1997) (holding that judges of the Coast Guard Court of Criminal Appeals need not be nominated by the President or confirmed by the Senate).

Petitioners nonetheless argue (Pet. 10-13) that special masters exercise authority that can only be conferred on superior officers nominated by the President and confirmed by the Senate. In petitioners' view (Pet. 12-13), that conclusion follows from the deferential standard of review under which the CFC and the Federal Circuit review special masters' factual determinations. That contention is wrong.

As this Court has explained, the fact that a judge exercises "significant authority on behalf of the United States" helps to show that the judge is an officer subject to the Appointments Clause, but does not mean that the judge is a superior officer, rather than an inferior one, and must therefore be nominated by the President and confirmed by the Senate. *Edmond*, 520 U.S. at 662-663. Instead, "[g]enerally speaking, the term 'inferior officer' connotes a relationship with some higher ranking officer or officers below the President: Whether one is an 'inferior officer' depends on whether he has a superior." *Id.* at 662. Here, the special masters have superiors—the judges of the CFC, who have authority to hire, fire, and determine the compensation of the special masters. 42 U.S.C. 300aa-12(c)(1), (2) and (5).

Edmond specifically refutes petitioners' contention (Pet. 13) that "[t]he power of a Court of Law to make *de novo* determinations has always been essential to the validity of the appointment of a subordinate official of that court." Superiors seldom have the time or resources to review *de novo* all of their subordinates' work, but that hardly means that the subordinates are not subordinates. Thus, this Court held in *Edmond*, contrary to petitioners' legal theory, that judges of the Coast Guard Court of Criminal Appeals are inferior officers even though their superior court, the Court of Appeals for the Armed Forces, exercises a "narrower" scope of review than the Court of Criminal Appeals by considering only whether "there is some competent evidence in the record to establish each element of the offense beyond a reasonable doubt." 520 U.S. at 665. There is no reason to apply a stricter standard in civil cases.*

Moreover, petitioners overstate the deference accorded to special masters. The CFC may "set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law." 42 U.S.C. 300aa-12(e)(2)(B). Claimants and the Secretary

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* Petitioners' reliance (Pet. 13) on *United States* v. *Raddatz*, 447 U.S. 667 (1980), is unavailing. *Raddatz*—which did *not* consider an Appointments Clause challenge—held that district judges are *not* required to rehear evidence heard by magistrate judges. *Id.* at 673, 676. *Raddatz* also upheld, against an Article III challenge, the district courts' discretion "to give to [a] magistrate's proposed findings of fact and recommendations 'such weight as [their] merit commands and the sound discretion of the judge warrants.'" *Id.* at 683 (quoting *Mathews* v. *Weber*, 423 U.S. 261, 275 (1976)).

may also appeal to the Federal Circuit. 42 U.S.C. 300aa-12(f).

Thus, contrary to petitioners' contention (Pet. 12), special masters' authority is not "unbridled." As the statute makes clear, a special master's legal conclusions are reviewed *de novo* by the CFC and the Federal Circuit under the "not in accordance with law" standard. 42 U.S.C. 300aa-12(e)(2)(B); see *Bradley* v. *Secretary of the Dep't of HHS*, 991 F.2d 1570, 1574 n.3 (Fed. Cir. 1993) ("Legal conclusions are, of course, always reviewed *de novo*."). Factual findings are also subject to review under the same "arbitrary and capricious" standard used in the Administrative Procedure Act (APA) and other statutes. See 42 U.S.C. 300aa-12(e)(2)(B) (Vaccine Act); 5 U.S.C. 706(2)(A) (APA). That degree of deference to special masters is integral to Congress's intent to create a "quick, flexible, and streamlined system" under which "awards [would] be made to vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. Rep. No. 247, *supra*, at 509; H.R. Rep. No. 908, 99th Cong., 2d Sess. 3 (1986).

Petitioners' attack on the Vaccine Act's incorporation of APA standards of review is difficult to square with their assertion (Pet. 10) that, as a remedial matter, this Court should "impose upon [the Vaccine Act] the strictures and procedural protections of the Administrative Procedures Act." A petitioner who is dissatisfied with the results of Vaccine Act proceedings has *greater* rights than a dissatisfied party in APA proceedings, because he may reject the Vaccine Act judgment and pursue a civil action for damages. 42 U.S.C. 300aa-21(a). In any event, the Appointments Clause analysis ultimately turns on whether special masters have superiors other

than the President (which they do), not on the extent to which their decisions are reviewed deferentially.

2. Nor does petitioners' due process claim warrant further review. The question presented in the petition asks (Pet. i) what "maximum judicial deference" may constitutionally be afforded to special masters. In contrast, the body of the petition (Pet. 14-18) advances a due process challenge to the Act's decisional structure, arguing that claimants are not fairly apprised of the issues or the applicable law. The latter contentions are not fairly included in the question presented, and do not warrant further review in any event.

a. Petitioners' broadside on the Vaccine Act's decisional structure was neither pressed nor passed upon below. In the lower courts, petitioners advanced the narrower, fact-bound claim that they lacked an opportunity to be heard on the specific question whether the onset of Richelle's alleged vaccine-related injury occurred within a medically acceptable time period following vaccination. See Pet. C.A. Br. 1. The CFC and the Federal Circuit both rejected that claim because the record shows that petitioners were on notice of the need to prove that the injury occurred within the required time period, and that petitioners in fact submitted evidence on that point. Pet. App. 49-51, 67-68. The lower courts' unanimous assessment of the factual record does not warrant this Court's review. Cf. *Graver Tank & Mfg. Co.* v. *Linde Air Prods. Co.*, 336 U.S. 271, 275 (1949) (explaining that the Court will not "undertake to review concurrent findings of fact by two courts below in the absence of a very obvious and exceptional showing of error").

In any event, the lower courts' assessment of the record is correct. Petitioners state (Pet. 2) that they

sought "to satisfy the legal causation-in-fact 'test' articulated * * * in the published opinion styled as *Stevens v. Secretary of DHHS*." As petitioners acknowledge (Pet. 2 n.2), that "test" includes "proof of a medically acceptable temporal relationship between the vaccination and the onset of the injury." Thus, petitioners were aware that, as part of their case-in-chief, they needed to prove a medically acceptable temporal relationship. Indeed, as the court of appeals noted, petitioners presented evidence on that issue through the testimony of Dr. Mark Geier, and argued below that Dr. Geier's testimony was "on all fours" regarding the timing issue. Pet. C.A. Br. 9, 35; see Pet. App. 67-68. As the court of appeals explained, "[w]hile Dr. Geier did not supply sufficient admissible evidence to satisfy this critical portion of the causation test, Pafford's admitted reliance on Dr. Geier in this regard impeaches her Due Process argument." Pet. App. 67-68.

b. Petitioners' broader contention that the Act's entire decisional structure violates the Due Process Clause was neither pressed nor passed upon below. It also lacks merit. Petitioners' contention is premised on the assertion (Pet. 15) that special masters have "unbridled discretion" to decide cases based on their own investigation, without affording claimants notice and an opportunity to be heard on the issues that may underlie the special masters' decisions. That is not correct.

The Vaccine Act provides:

> In conducting a proceeding on a petition, a special master—
>
> > (i) may require such evidence as may be reasonable and necessary,

(ii) may require the submission of such information as may be reasonable and necessary,

(iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,

(iv) *shall* afford all interested persons an opportunity to submit relevant written information—(I) relating to the existence of the evidence described in section 300aa-13(a)(1)(B) of this title, or (II) relating to any allegation in a petition with respect to the matters described in section 300aa-11(c)(1)(C)(ii) of this title, and

(v) may conduct such hearings as may be reasonable and necessary.

42 U.S.C. 300aa-12(d)(3)(B) (emphasis added).

Thus, the Act requires the special master to afford interested persons an opportunity to submit written information regarding causation. 42 U.S.C. 300aa-12(d)(3)(B)(iv). And a special master's other decisions concerning the presentation of evidence are reviewed for abuse of discretion. 42 U.S.C. 300aa-12(e). Special masters must also enter findings of fact and conclusions of law on the record. 42 U.S.C. 300aa-12(d)(3)(A)(1). On their face, those statutory provisions are sufficient to safeguard due process. And as discussed, there is no as-applied concern in this case, because petitioners had notice and an opportunity to be heard on the dispositive time frame issue.

Petitioners' related suggestion (*e.g.*, Pet. 8-9) that special masters invent *ad hoc* legal standards in individual cases is also incorrect. Proceedings are governed by the statute, as construed by the Federal Circuit. While

petitioners complain that decisions of special masters and CFC judges do not establish binding precedents for subsequent cases, see Pet. 9 n.15 (citing *Hanlon* v. *Secretary of HHS*, 40 Fed. Cl. 625, 630 (1998), aff'd, 191 F.3d 1344 (Fed. Cir. 1999), cert. denied, 530 U.S. 1210 (2000)), trial court decisions are not ordinarily precedential. Instead, appellate courts, including the Federal Circuit here, establish precedents binding on trial courts. Cf. *Althen* v. *HHS*, 418 F.3d 1274, 1281 (Fed. Cir. 2005) ("The special master's role is to assist the courts by judging the merits of individual claims on a case-by-case basis, not to craft a new legal standard."). That hardly makes trial court adjudications arbitrary or unconstitutional.

While Vaccine Act proceedings do not follow the same procedures as civil actions, the reason is that Congress desired a quicker, more streamlined procedure for compensating claimants. H.R. Rep. No. 908, *supra*, at 3. And a claimant who is dissatisfied with an award under the Act may reject it and bring an ordinary tort action in court. 42 U.S.C. 300aa-11(a), 300aa-21. Congress's use of more informal procedures in that context than in the context of binding civil adjudication does not violate the Due Process Clause.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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MAY 2007